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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,665	09/09/2003	Doug Holc	0-03-192	2000

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/658,665	HOLE ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *4-8,10,12,14 and 16-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9,11 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/9/03, 6/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the restriction between Groups I and II in the reply filed on 26 April 2007 is acknowledged. The traversal is on the ground(s) that the claimed methods overlap in scope and are not mutually exclusive. This is not found persuasive because the method in Group I comprises the step of providing an extracorporeal circuit along with the other steps and limitations of the claims, and the method of Group II requires the step of providing a cardiopulmonary bypass along with the other steps and limitations of the claims. The methods are, in fact, different in scope, since the steps of providing each type of processing circuit are materially different and have acquired a status that is different from one another in the art.

2. Applicant's amendment to claim 15 brings it within the scope of Group I and is rejoined for prosecution.

The requirement is still deemed proper and is therefore made FINAL.

3. Accordingly, claims 1-3, 9, 11, 13, 15, and 26 are examined herein.

Information Disclosure Statement

4. The references cited by applicants in the information disclosure statements filed 9 September 2003 and 18 June 2007 have been made of record. Examiner has considered the voluminous references to the best of her ability.

While the statements filed do not comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the eliminaiton of clearly irrelevant

art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 does not require that the information be material; rather, they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references. However, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure. *See* Penn Yan Boats, Inc. v. Sea Lark boats Inc., 359 F. Supp. 948, *aff'd* 479 F. 2d. 1338.

Applicant is advised that the MPEP states the following with respect to large information disclosure statements:

> *Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability.* MPEP § 609.04(a)(III).

This statement is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), states that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888.

The MPEP provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

> *It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted,*

> *highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See* Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5th Cir 1974). *See also* MPEP § 2004.

Therefore, it is recommended that if any information that has been cited by Applicants in the previous disclosure statement is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3, 11, 13, 15, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,492 to Igo in view of Croen (Croen, KD, *Evidence for an antiviral effect of Nitric Oxide*. J Clin Invest 91:2446-2452, 1993).

In the specification and figures, Igo discloses the apparatus and method substantially as claimed by applicant. With regard to claims 1 and 15, Igo discloses a device and method for exposing a patient's blood to nitric oxide within an extracorporeal circuit. The method comprises the steps of providing an extracorporeal circuit 10 with an inlet 14 and outlet 48 that communicate with the patient, a fluid circuit, and at least one pump 22 (see FIGS 1-2). The method comprises the steps of circulating blood through

the circuit and exposing the blood in the circuit to nitric oxide from a source (see column 4, lines 5-48).

Igo fails to disclose that the NO exposure is sufficient to reduce pathogenic content in the blood, but does disclose that the device comprises a means to control the administration of NO to the blood in the circuit in order to achieve a desired result. Croen teaches that NO exerts microbiostatic, microbiocidal, and antiviral effects on pathogens (see p 2446). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify the method disclosed by Igo to expose the blood to an amount of NO sufficient to reduce pathogens in the blood in order to engage the antibiotic and antiviral effects of NO, as taught by Croen.

With regard to claims 2-3, the Igo device and method may comprise a blood treatment component (such as a dialyzer, oxygenator, or heat exchanger) with one NO feed device located upstream of the treatment component (see column 4, lines 15-25).

With regard to claim 11, Igo discloses that the system and method may comprise the step of administering the NO with a carrier gas (see column 7, lines 25-35).

With regard to claims 13 and 26, Igo discloses that the device and method comprise the step of feeding the blood through a scavenger unit 67 to absorb residual NO (see column 7, lines 39-45).

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,492 to Igo in view of Croen, further in view of McInnes et al (McInnes IB, Leung B, Wei, X-Q, Gemmell CG, and FY Liew. *Septic Arthritis Following* Staphylococcus aureus *infection in mice lacking inducible Nitric Oxide Synthase.* J Immun. 160: 308-315, 1998).

Igo and Croen disclose the method substantially as claimed by applicant (see rejection above) with the exception of targeting septicemia during the method. McInnes discloses that NO production appears to reduce septicemia in mice, suggesting that NO exposure might be a successful treatment for sepsis (see page 313). Accordingly, it would have been obvious to one having ordinary skill in the art at the time of invention to use the method suggested by Igo and Croen to target septicemia as suggested by McInnes in order to control sepsis.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 6,287,608 Levin

i. Use of NO donors for vasodilation

b. US 6,878,127 Brady

ii. NO coatings on medical devices to reduce infection

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
2 July 2007